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CENTRAL REEXAMINATION UNIT

Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith are a copies of applications for patent term extension of U.S. Patent Nos. 5,782,919 and 5,984,967. Both of the applications were filed on August 30, 2002, under 35 U.S.C. § 156.

The patents claim a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571)272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Christopher A. Brown
Woodard Emhardt Moriarty McNett and Henry
Bank One Tower/Center
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137

RE: InFuse® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device
FDA Docket No. 03E-0243 and 03E-0244